

We Claim:

1. A pharmaceutical dosage form suitable for the administration of NSAIDS and/or
5 acetaminophen in a liquid suspension, said dosage form comprising:
- a) a first portion containing an NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the dosage form in a substantially immediate manner upon contact of the dosage form with a dissolution medium; and
 - b) a second portion of particles containing NSAID and/or acetaminophen, said NSAID
10 and/or acetaminophen being released from the particles in a controlled manner upon contact of the dosage form with the dissolution medium,
- wherein the pharmaceutical dosage form has a duration of therapeutic effect for at least about 8 hours after its administration.
- 15 2. The dosage form of claim 1 further comprising a vehicle for the administration of the first portion and the second portion.
3. The dosage form of claim 2, wherein the vehicle is comprised of one or more agents selected from the group consisting of suspending systems, surfactants, sweeteners,
20 buffering agents, preservatives, flavoring agents, and mixtures thereof.
4. The dosage form of claim 2, wherein the vehicle is comprised of water, and the dosage form is in the form of a liquid suspension.
- 25 5. The dosage form of claim 1, wherein said particles in said second portion are comprised of a core that is substantially covered by a coating thereon, and said coating is comprised of a controlled release composition.
6. The dosage form of claim 1, wherein said particles in said second portion are
30 dispersed in a matrix, and said matrix is comprised of a controlled release composition.
7. The dosage form of claim 4, wherein said particles in said second portion are comprised of a core that is substantially covered by a coating thereon, and said coating is comprised of a controlled release composition.

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8. The dosage form of claim 5, wherein said controlled release composition is comprised of, based upon the total weight of the controlled release composition, from greater than about 0 percent and less than about 100 percent of an insoluble film forming polymer and from about 0 percent to less than about 10 percent of an enteric polymer.

9. The dosage form of claim 7, wherein said controlled release composition is comprised of, based upon the total weight of the controlled release composition, from greater than about 0 percent and less than about 100 percent of an insoluble film forming polymer and optionally from about 0 percent to less than about 10 percent of an enteric polymer.

10. The dosage form of claim 7, wherein said controlled release composition is substantially free of enteric polymers, and the pKa of at least one active ingredient contained in said second portion of particles is greater than the pH of the liquid suspension.

11. The dosage form of claim 8, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer in the controlled release composition is from about 80:20 to about 99:1.

12. The dosage form of claim 9, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer in the controlled release composition is from about 80:20 to about 99:1.

13. The dosage form of claim 11, wherein the insoluble film forming polymer is selected from the group consisting of cellulose acetate, ethylcellulose, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) in a 1:2:0.1 weight ratio, and mixtures thereof.

14. The dosage form of claim 11, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, polyvinylacetate phthalate, polymethacrylate-based polymers, and copolymers and mixtures thereof.

15. The dosage form of claim 14, wherein the polymethacrylate-based polymer is poly(methacrylic acid, methyl methacrylate) in a weight ratio of 1:2 and/or poly(methacrylic acid, methyl methacrylate) in a weight ratio of 1:1.

16. The dosage form of claim 12, wherein the insoluble film forming polymer is selected from the group consisting of cellulose acetate, ethylcellulose, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) in a 1:2:0.1 weight ratio, and mixtures thereof.

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17. The dosage form of claim 12, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, polyvinylacetate phthalate, polymethacrylate-based polymers, and copolymers and mixtures thereof.

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18. The dosage form of claim 17, wherein the polymethacrylate-based polymer is poly(methacrylic acid, methyl methacrylate) in a weight ratio of 1:2 and/or poly(methacrylic acid, methyl methacrylate) in a weight ratio of 1:1.

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19. The dosage form of claim 5 wherein the coated particles in said second portion are comprised of, based upon the total dry weight of the coated particles in the second portion, from about 10 percent to about 40 percent of the controlled release composition.

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20. The dosage form of claim 7 wherein the coated particles in said second portion are comprised of, based upon the total dry weight of the coated particles in the second portion, from about 10 percent to about 40 percent of the controlled release composition.

21. The dosage form of claim 5, wherein the NSAID is a propionic acid derivative NSAID.

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22. The dosage form of claim 7, wherein the NSAID is a propionic acid derivative NSAID.

23. The dosage form of claim 1 comprised of, based upon the total weight of the active ingredient:

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- a) from about 25 percent to about 75 percent of active ingredient in the first portion; and
- b) from about 75 percent to about 25 percent of active ingredient in the second portion.

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24. The dosage form of claim 1, wherein said therapeutic effect is pain relief.

25. The dosage form of claim 1, wherein the pharmaceutical dosage form is a liquid suspension, and the pKa of at least one active ingredient contained in said second portion of particles is greater than the pH of the liquid suspension pharmaceutical dosage form.

- 5 26. A liquid suspension dosage form comprising: ✓
- a) a first portion containing an NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the dosage form in a substantially immediate manner upon contact of the dosage form with a dissolution medium;
 - 10 b) a second portion of particles containing NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the particles in a controlled manner upon contact of the dosage form with the dissolution medium; and
 - c) water, or mixtures of water and a pharmaceutically acceptable water-miscible co-solvent selected from the group consisting of glycols, alcohols, and glycerol,
 - 15 wherein the dosage form has a duration of therapeutic effect for at least about 12 hours after administration.

27. The liquid suspension dosage form of claim 26 comprising, based upon the total weight of the liquid suspension dosage form:

- 20 a) from about 0.25 percent to about 30 percent of a first portion containing an NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the dosage form in a substantially immediate manner upon contact of the dosage form with a dissolution medium;
- 25 b) from about 0.0125 percent to about 0.025 percent of a second portion of particles containing NSAID and/or acetaminophen, said NSAID and/or acetaminophen being released from the dosage form in a controlled manner upon contact of the dosage form with the dissolution medium; and
- 30 c) from about 20 percent to about 70 percent of water, or mixtures of water and a pharmaceutically acceptable water-miscible co-solvent selected from the group consisting of glycols, alcohols, and glycerol,
- wherein the dosage form has a duration of therapeutic effect for at least about 12 hours after administration.

28. The dosage form of claim 26 wherein the first portion and the second portion are suspended in component c).

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29. A method for treating pain in a mammal in need thereof, which comprises administering the dosage form of claim 1 in an amount effective for providing pain relief to the mammal for a period of at least about 12 hours after administration of the dosage form.

5 30. A method for treating pain in a mammal in need thereof, which comprises administering the dosage form of claim 26 in an amount effective for providing pain relief to the mammal for a period of at least about 12 hours after administration of the dosage form.

10 31. A method of administering acetaminophen and/or an NSAID in a pharmaceutical dosage form to a mammal in need thereof, said method comprises providing to a mammal said dosage form such that the mammal receives an immediate release dose of said acetaminophen and/or NSAID at the beginning of said 12 hour time period, and a controlled release dose of said acetaminophen and/or NSAID over a period of about 12 hours after administration of said dosage form, wherein no further acetaminophen and/or NSAID is provided during said 12 hour time
15 period.